

<b>Notice of Allowability</b>	Application No.	Applicant(s)	
	09/167,516	CHEEVER ET AL.	
	Examiner Karen A Canella	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1:313 and MPEP 1308.

1.  This communication is responsive to \_\_\_\_\_.
2.  The allowed claim(s) is/are 8, 9, 11, renumbered as 1-3, respectively.
3.  The drawings filed on 06 October 1998 are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
 of the:
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
7.  IDENTIFYING INDICIA such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

  
**KAREN A. CANELLA PH.D**  
**PRIMARY EXAMINER**

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Richard Sharkey on January 11, 2005.

The application has been amended as follows:

Claim 7 has been canceled.

Claim 8 has been replaced with the following:

8. A method for eliciting or enhancing an immune response to HER-2/neu protein , comprising transfecting antigen presenting cells of a warm-blooded animal ex vivo with a nucleic acid molecule and subsequently delivering the transfected cells to the animal in an amount effective to elicit or enhance said response, wherein the nucleic acid molecule directs the expression of a polypeptide encoded by a DNA sequence selected from:

(a) nucleotides 2026 through 3765 of SEQ ID NO:1, and  
(b) DNA sequences that hybridize to a nucleotide sequence complementary to nucleotides 2026 through 3765 of SEQ ID NO:1 under moderately stringent conditions, wherein the DNA sequence encodes a polypeptide that produces an immune response to HER-2/neu protein, and wherein the hybridization conditions comprise prewashing in a solution of 5X SSC, 0.5% SDS, 1.0mM EDTA (pH 8.0); hybridization at 50° to 65° C in 5X SSC overnight; followed by washing twice at 65° C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS, with the proviso that the polypeptide of (b) is not intact HER-2/neu protein.

Claim 9 has been replaced with the following:

9. A method for eliciting or enhancing an immune response to HER-2/neu protein , comprising infecting antigen presenting cells of a warm-blooded animal ex vivo with a viral vector and subsequently delivering the infected cells to the animal in an amount effective to elicit

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or enhance said response, wherein the viral vector directs the expression of a polypeptide encoded by a DNA sequence selected from:

(a) nucleotides 2026 through 3765 of SEQ ID NO:1, and

(b) DNA sequences that hybridize to a nucleotide sequence complementary to nucleotides 2026 through 3765 of SEQ ID NO:1 under moderately stringent conditions, wherein the DNA sequence encodes a polypeptide that produces an immune response to HER-2/neu protein, and wherein the hybridization conditions comprise prewashing in a solution of 5X SSC, 0.5% SDS, 1.0mM EDTA (pH 8.0); hybridization at 50° to 65° C in 5X SSC overnight; followed by washing twice at 65° C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS, with the proviso that the polypeptide of (b) is not intact HER-2/neu protein.

Claim 11 has been replaced by the following:

11. The method of claims 8 or 9 wherein the polypeptide has the amino acid sequence of SEQ ID NO:2 from amino acid 676 through amino acid 1255.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

1/11/2005

*Karen A. Canella*  
KAREN A. CANELLA PH.D  
PRIMARY EXAMINER